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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/180,657	11/12/98	MEIKLE	P 2325-1-002

HM12/0830

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EXAMINER

NOLAN, P

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED:

08/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/180,697

Applicant(s)

Nickle et al.

Examiner

Nolan

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/16/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 52-94 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 52-94 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. Claims 52-92 are pending.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52-74 and 84-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's disclosure is not enabled for the recitation of the terms immunologically active homologue, analogue or derivative thereof. There are no working examples nor specific guidance as to what an immunologically active homologue, analogue or derivative thereof is and whether or not it can be detected and whether or not its detection will correlate to a lysosomal storage disorder. The state of the art., Colman et al., teaches that single amino acid changes in a protein which create whole new epitopes and since Applicant's specification does not teach what changes are encompassed by the terms immunologically active homologue, analogue or derivative thereof it would be unpredictable and require an undue amount of experimentation to practice Applicant's claimed invention.

4. Claims 75-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting an increase in LAMP-1 expression and correlating said increase to an LSD, does not reasonably provide enablement for the detection of an LSD and the increase of any LSD marker. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicants specification clearly teaches it is unpredictable whether or not a LSD marker will be increased and whether or not said increase correlates to the detection of an LSD. Table 3 clearly teaches that different markers are upregulated for different diseases, while in other diseases there is no correlation, in addition page 30, lines 4-10, clearly teach that LAMP-2 levels decreased in some LSD affected individuals. In addition Michelakakis et al., (of record), teaches that an LSD, glucocerebrosidase levels went down in LSD affected people. Since the state of the art and Applicant's own working examples clearly

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Art Unit: 1644

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teach it is unpredictable whether or not an LSD marker will be increased and detect an LSD it would require an undue amount of experimentation to practice the full breadth Applicant's claimed invention.

5. Claims 52-74 and 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claims 52 and 93 are indefinite because they recite no correlation steps. In an assay to detect or diagnose a disease once the compound is detected, its detection must be correlated to the disease to be definite.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
August 28, 2000